

**REMARKS****Amendments to the Claims**

Claims 1, 2, 5-12, 15-27, and 30-36 were pending in the present application. Applicants have amended claims 1, 2, 8, 19, 21-24, and 36. New claim 37 has been added.

Claims 1 and 2 have been amended to replace the variable " $X_n$ " with the variable "X." Support for this amendment can be found in original claims 1 and 2 and throughout the specification, including for example on page 3.

Claim 8 has been amended to delete the phrase "...that is not naturally occurring." Support for this amendment can be found in original claim 8 and on page 12, lines 16-17.

Claims 19, 21 and 22 have been amended to clarify that which the Applicants regard as the claimed invention. Support for the amendment to claim 19 can be found on page 39, lines 15-18. Support for the amendment to claims 21 and 22 can be found on page 40, lines 10-16.

Claims 23 and 24 have been amended to distinguish trade names from generic names of chemical compounds. Claim 23 has also been amended to properly depend from claim 22. Support for these amendments can be found in originally filed claims 23 and 24.

Claim 36 has been amended to delete subject matter that was canceled from amended claim 23. Claim 37 was added to recite subject matter that was canceled from amended claim 23. Support for amended claim 36 and new claim 37 can be found throughout the specification and in original claim 23.

Accordingly, upon entry of the instant amendments, claims 1, 2, 5-12, 15-27, and 30-37 will be pending in this application. None of the amendments introduces new matter.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claims 1, 2, 5-12, 15-27, 30 and 33-36 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way to enable one of skill in the art to make and/or use the invention. In particular, the Office Action asserts that "the scope is unduly broad in view of the enabling disclosure." Office Action at 3. For the following reasons, Applicants respectfully traverse this ground of rejection.

***The Office Action fails to Establish a Prima Facie Case of Nonenablement***

The Office Action states, as a rationale for the enablement rejection, "that 'undue experimentation' would be required to determine which of the claimed compounds can exhibit antibacterial activity." Office Action at 5. After reciting the eight *Wands* factors, the Office Action attempts to support this rationale by citing five references which discuss antibiotics that are unrelated to applicants claimed compounds. Office Action at 3-4. The Office Action then asserts that:

These and other references disclose that there do exist compounds which exhibit antibacterial activity, and many of these inactive compounds are structurally analogous to compounds that are active. The key point is that the factors which give rise to activity or inactivity are unknown in the art; and certainly the specification has made no attempt to discuss such factors. Accordingly, the skilled microbiologist cannot predict antibacterial activity merely by viewing a structure.

\* \* \*

It remains the case that "undue experimentation" would be required to determine which of the claimed compounds can exhibit antibacterial activity.

Office Action at 4-5.

Assuming for the sake of argument that the above statements are true, these statements are irrelevant to whether or not the pending claims are enabled by Applicants' C058 Response to 070904OA 01-10-05 FINAL 28

specification. That is, the enablement requirement does not require Applicants or skilled microbiologists to "predict antibacterial activity merely by viewing a structure." Rather, to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, Applicants' specification must describe how to make and use the claimed invention in such a way that one of ordinary skill in the art would understand how to make and use the claimed invention. See MPEP § 2164 (8<sup>th</sup> ed., Rev. May 2004). Thus, what is relevant to the question of enablement is what is Applicants' disclosure of how to make and use the claimed invention. Accordingly, the Office Action has not established a prima facie case of nonenablement with respect to the presently pending claims.

***Applicants Have Satisfied the Enablement Requirement by Sufficiently Disclosing How to Make and Use the Claimed Invention***

Applicants' specification describes the synthesis of more than sixty compounds. See Examples 1, 1a, 1b, 2, 2a, 2b, 2c, 3, 3a, 3b, 4, 4a and 4b on pages 54-63. This disclosure is more than sufficient to teach one of ordinary skill in the art how to make the compounds of the claimed invention. Applicants' specification also provides *in vitro* antibacterial data for more than sixty compounds. As described in Example 5 on page 63:

Compounds according to Formula I were tested for antimicrobial activity against a panel of organisms according to standard procedures described by the National Committee for Clinical Laboratory Standards (NCCLS document M7-A5, Vol. 20, No. 2, 2000) except that all testing was performed at 37°C.

Thus, any additional testing to determine antibacterial activity would be routine, not undue. If anything, the references cited in the Office Action demonstrate that testing for antibacterial activity is routine in the art.

In addition, Applicants' specification describes and teaches *in vivo* testing of the claimed invention. Specifically, in Example 6, Applicants describe determining the

antibacterial activity of Compound 2 in mice. Results of Applicants' antibacterial testing are provided in Table VI.

Finally, Applicants' specification provides abundant guidance on using the claimed invention in pharmaceutical compositions and for the treatment of bacterial infections. *See e.g.* pages 32-41. Thus, for all of the foregoing reasons, the presently pending claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 1, 2, 5-12, 15-17, and 30-36 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention.

The Office Action states that claims 1 and 2 contain the variable " $X_n$ "; however, " $n$ " can assume only 1 value. The Office Action states that making reference to variable " $X_n$ " and then defining " $n$ " as 1 is superfluous. Applicants have amended claims 1 and 2 to replace the variable " $X_n$ " with the variable " $X$ " as suggested by the Examiner.

The Office Action states that claim 19 makes reference to "antibiotic-resistant bacteria" but does not exclude resistance to the claimed compounds. Applicants have amended claim 19 to state that the antibiotic-resistant bacteria are resistant to an antibiotic that is not included within the scope of Formula (1).

Claim 21 is objected to because the claim makes reference to "a compound of Formula (I)" but does not define which version of Formula (I) is being referred to in the claim. Applicants have amended the claim to recite a compound of Formula (I) "according to either of claims 1 or 2."

The Office Action states that the clarity of claim 22 would be improved by making reference to a "second antimicrobial agent." As suggested by the Examiner, Applicants have amended the claim to recite a second antimicrobial agent and to recite that the second antimicrobial agent is not included within the scope of Formula (1).

The term "synthetic antibacterials" is objected to in the Office Action because it overlaps with the other terms recited and generates redundancy. Applicants have deleted the term "synthetic antibacterials."

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

#### Trademarks

The Office Action states that claim 23 and 24 are objected to because "trademarks should be capitalized (e.g. ZIRACIN, SYNERCID, EPIROPRIM)." Applicants have amended claims 23 and 24 to capitalize the trademarks ZIRACIN and SYNERCID. Applicants assert that the other chemical terms are generic names. Applicants have amended claims 23 and 24 so that all generic names are recited without capitalization.

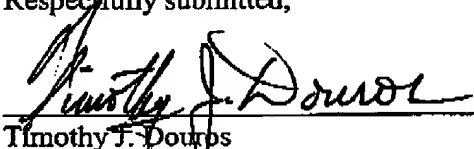
Applicants respectfully request reconsideration and withdrawal of this objection.

## CONCLUSION

For the reasons presented above, Applicants respectfully request reconsideration and prompt allowance of all pending claims. A petition for a three month extension of time to extend the time for responding to and including January 10, 2005 is being filed concurrently herewith. No additional fee is believed due in connection with the filing of this Amendment. However, the Commissioner is authorized to deduct any deficient amount or credit any surplus amount to Deposit Account No. 50-1986.

Respectfully submitted,

Dated: January 10, 2005  
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